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(54) Process for preparing fatty fodder additives for producing meat with high content omega-3-fatty acids

(57) A process for preparing a fatty fodder additive for domestic animals which additive increases the content of omega-3-fatty acids within the meats when the fodder additive is fed to the animal comprises mixing an emulsifier, a carrier material and a vegetable oil, animal fat or fatty acid to obtain an emulsion, drying and atomizing the emulsion in a drier, coating the resulting powdered fat with an enteric coating material and drying it.

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the product made from fatty acid salts has the problem of greatly increasing the speed of fat oxidation as the chemical state changes from triglyceride, ester, free fatty acid, to metal salt of fatty acid in that order, consequently 80 to 90% of the fatty acid within the free fatty acid salt becomes saturated fatty acid. Furthermore, since most of the spray-dried products are produced for humans, the practical fat content thereof ranges from 5 to 40%, and thus they have economic disadvantages when used for fodder supplied to domestic animals because of the lower fat content. There is also a problem of autooxidation during the long storage. Since the liberation of metal components, Ca or Na, from the fatty acid proceeds slowly, because of the acidity of the stomach, and because of the higher melting points of these salts, animals cannot normally absorb the fatty acids in the small intestine.

According to the present invention there is provided a process for producing fatty fodder additives which comprises mixing an emulsifier and a carrier material into a vegetable oil, animal fat or fatty acid, to obtain an emulsion, drying and atomizing the emulsion in a drier to give a powdered fat and coating it with an enteric coating material. The fatty fodder additives thus obtained can be used for increasing the content of omega-3-fatty acids, ie, linolenic acid, eicosapentaenoic acid and docosahexaenoic acid, and for lowering the cholesterol content within the meat by feeding them to domestic animals so that the absorption rate of fatty acids is constantly maintained.

Extensive studies have been made in order to solve the above problems in the prior art and

peristaltic pump, and then the emulsion of (a) was sprayed and atomized.

Primary powdered fat thus obtained has a particle size ranging from 0.1 to 1.0 mm and the fat content thereof may be 5% or more.

Then, magnesium stearate, silicon oxide (SiO_2), vitamins, minerals, antibiotics and celluloses each in a suitable amount may be be added to the powered fat. Separately, cellulose such as ethyl cellulose, cellulose acetate phthalate, hydroxypropyl methyl cellulose, hydroxypropyl cellulose or methyl cellulose, or shellac as an enteric coating material was dissolved in a solvent to a final concentration of from 1 to 10%. Finally, the powdered fat was coated with 100 ml of the enteric coating material in a coater to obtain a fatty fodder additive having a particle size of from 0.5 to 2.0 mm.

The process for preparing a fatty food additive in accordance with this invention will be further described by way of reference to the following Example.

Example

Step 1: Atomization of fat

(a) Preparation of 30% powdered fat

To a mixture of 50 g of fish oil and 50 g of soybean oil was added 5 g of Tween 60 as an emulsifier, and the resulting mixture was heated to 50 °C, to which was added 300 g of whey, and then it was homogenized to obtain an emulsion. Into a fluid bed drier, a mixture of 100 g of soybean protein and 100 g of corn starch as a seed material was charged. The emulsion was dried by spraying it from the top of the drier while fluidizing the seed material by inflowing air adjusted to 50 °C to obtain powdered

Step 2: Coating of powdered fat obtained in Step 1 with enteric coating material and drying.

(a) 200 g of 30% powdered fat obtained in Step 1 was charged into a fluid bed coater, and a solution obtained by dissolving 5 g ethyl cellulose in 100 ml of methyl alcohol was sprayed to coat the powdered fat with an ethyl cellulose film, thereby obtaining the desired product.

(b) 100 g of 50% powdered fat obtained in Step 1 was charged into a fluid bed coater, and a solution obtained by dissolving a mixture of 2.1 g hydroxypropylmethyl cellulose and 0.9 g of sodium carboxymethyl cellulose in 100 ml of water was sprayed to coat the powdered fat with a film of hydroxypropyl methyl cellulose and sodium carboxymethyl cellulose, thereby obtaining the desired product.

(c) After charging 200 g of 70% powdered fat obtained in Step 1 into a fluid bed coater, a mixture of 10 g magnesium stearate, 10 g of Avicell and 10 g of silicon oxide was added thereto, and the mixture was coated with a solution of cellulose acetate phthalate (7.5 g) in 100 ml of acetone to give the desired product.

The fatty fodder additives prepared according to this invention have the following advantages.

1. Meats in which the content of unsaturated fatty acids, particularly omega-3-fatty acid is high but that of cholesterol is low can be produced when the present additives were fed to domestic animals.

2. It has a moderate hardness for domestic animals to eat.

3. It can be added to formula feeds, or

Table 1. Changes in amount of omega-3-fatty acids accumulated in the microsome of the liver.

content fatty acid	fatty acids in microsome (%) a	b	c	d	e
Linolenic acid	0.37	0.29	8.27	11.30	0.91
Eicosapentaenoic acid	0.65	0.29	7.74	10.72	7.25
Docosapentaenoic acid	1.70	1.21	2.54	4.20	2.61
Docosahexaenoic acid	3.70	2.20	2.00	3.50	9.29
total omega-3-fatty acids	6.42	3.99	20.55	29.72	20.26

Table 2. Changes in amount of omega-3-fatty acids accumulated in the loin.

content fatty acid	fatty acids in loin (%) a	b	c	d	e
Linolenic acid	0.48	0.44	4.57	7.45	2.47
Eicosapentaenoic acid	0.53	0.15	1.05	2.72	2.25
Docosapentaenoic acid	0.56	0.24	1.00	2.24	3.26
Docosahexaenoic acid	0.85	0.25	0.85	1.75	8.08
total omega-3-fatty acids	2.42	1.08	7.47	14.16	16.06

CLAIMS

1. A process for preparing fatty fodder additives which comprises mixing an emulsifier and a carrier material into a vegetable oil, animal fat or fatty acid to obtain an emulsion, drying and atomizing the emulsion in a drier, coating the resulting powdered fat with an enteric coating material and drying it.

2. A process according to Claim 1, wherein the fat is selected from soybean oil, perilla oil, fish oil, linseed oil, crude soybean lecithin, red pepper seed oil or mixtures thereof.

3. A process according to Claim 1 or Claim 2, wherein the fat or fatty acid employed has a fatty acid composition of at least 2% eicosapentaenoic acid and at least 2% docosahexaenoic acid.

4. A process according to Claim 1 or Claim 2, wherein the fat or fatty acid employed has a fatty acid composition of at least 2% linolenic acid, at least 2% eicosapentaenoic acid and at least 2% docosahexaenoic acid.

5. A process according to Claim 1 or Claim 2, wherein the fatty acid composition is at least 5% total phospholipid, at least 2% linolenic acid, at least 2% eicosapentaenoic acid and at least 2% docosahexaenoic acid when crude soybean lecithin is used.

6. A process according to Claim 5, wherein the fatty acid composition is at least 10% total phospholipid and at least 5% linolenic acid when crude soybean lecithin is used.

7. A process according to any one of Claims 1 to 6, wherein the carrier material is selected from soybean protein, skim milk, starch, pectin, gelatin, collagen, casein, egg protein and the like.

PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
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(54) Title: A GRANULATE CONTAINING GAMMA LINOLENIC ACID, EICOSAPENTAENOIC ACID AND/OR DOCOSAHEXAENOIC ACID, THE METHOD FOR ITS MANUFACTURING, ITS USE IN EDIBLE PRODUCTS, AND A TABLET CONTAINING IT

(57) Abstract

A granulate comprising an oil-powder mixture containing 2-75 % vegetable oil and/or marine oil containing essential fatty acids selected from gamma linolenic acid (GLA), eicosapentaenoic acid (EPA) and/or docosahexaenoic acid (DHA) and/or other marine oils and a water-soluble carrier, in combination with a solid pulverulent filler and a binder. Tablets containing said granulate. Use of said granulate and tablets in pharmacy, dietary supplements, food products and fodder.

A granulate containing gamma linolenic acid, eicosapentaenoic acid and/or docosahexaenoic acid, the method for its manufacturing, its use in edible products, and a tablet containing it.

Field of the invention

The present invention relates to a granulate comprising an oil-powder mixture containing 2-75 % oil concentration of vegetable and/or marine oils and a water-soluble carrier in combination with a solid pulverulent filler and a binder, and to the preparation of said granulate, use of said granulate especially for the preparation of tablets, as well as said tablets.

Background of the invention

Currently available vegetable and marine oils containing essential fatty acids are administrated in fluid form in bottles, containers or in soft or hard gelatin capsules. Particularly, this applies to oils containing gamma linolenic acid (GLA), eicosapentaenoic acid (EPA) or docosahexaenoic acid (DHA).

A great disadvantage with these oils in oil phase is that they can not be mixed with water-soluble substances.

A long-felt want is to prepare tablets comprising a high content of the essential fatty acids GLA, and/or EPA/DHA, since tablets are an administration form easy of access. However, a lot of practical and technical problems have prevented the preparation of such tablets. Surprisingly, the preparation of a granulate according to the present invention has been capable of solving these problems.

Description of the invention

The object of the present invention is to prepare a granulate, having a high content of fatty acids and compressability properties especially suitable for the preparation of tablets for application in pharmacy, dietary supplements, food products and veterinary medicine.

The preparation of the oil-powder mixture is in the following way:

(i) heating the oil to e.g. 20-70°C depending on the oil used; optionally adding of an antioxidant a monoglyceride preferably 0,1-1,0 % (monoglyceride w/oil w) vegetable monoglyceride with vigorous stirring. The monoglyceride makes the homogenisation easier.

(ii) simultanously, a defatted carrier is dissolved in water with vigorous stirring and heating from e.g. 20°C to 65°C depending on the carrier used,

(iii) the mixture (i) containing the oil and the mixture (ii) containing the carrier in water solution are mixed with vigorous stirring,

(iv) the resulting mixture is then emulsified by means of a conventional high pressure homogenizer working at a pressure above 100 kg/cm^2 (100-250 kg/cm^2),

(v) the emulsion formed is dried in a conventional spray-drier. The emulsion out-coming from the nozzle meet warm air having a temperature about 200°C. The powder formed in the spray-drier has a temperature of about 70°C, which can be lowered to room temperature (18-23°C) by passing a fluid-bed drier or similar device.

The oil-powder mixture has an average particle size of from 0,1 to 1,5µ, at agglomeration the particle size increases. The oil concentration of the oil-powder mixture may vary from 2 % to 75 % especially from 20 % to 75 % (w/w) preferably between 40 % to 75 % (w/w) depending on the amount of oil being added to the carrier solution (step iii above).

The preparation of the granulate of the present invention is performed in the following way:

(a) dry-mixing the oil-powder mixture, optionally containing an antioxidant, with a solid, pulverulent filler preferably dextrose, optionally adding of a diluent, with vigorous stirring,

size containing a sufficient amount of active substance. Several people prefer tablets to capsules owing to taste, design, easier to swallow etc.

Tablets of the present invention are especially suitable as chewing tablets or effervescent tablets. The chewing tablets may also include vegetable fibres. Incorporation of an acid/bicarbonate mixture e.g. a tartaric acid/sodium bicarbonate mixture, make the tablets effervescent on addition of water.

The tablets are prepared by pressing the granulate obtained optionally with addition of additives in a conventional tableting machine.

Additives can optionally be added in the preparation of the granulate and/or in preparation of the tablets.

The invention will be illustrated by the following examples without being limited thereto.

Example 1 Oil-powder mixture, 50 % borage oil

Components

Soybean protein	480 kg
Borage oil	480 kg
Water	1 760 l
Vegetable monoglyceride	1 kg

Soybean protein was dissolved in water with vigorous stirring and heating to about 65°C. Borage oil containing antioxidant was heated to 65°-70°C and monoglyceride was added with vigorous stirring. The borage oil was mixed with the aqueous soybean protein solution with vigorous stirring. Then the mixture obtained was pumped to a conventional homogenizer working at a pressure above 100 kg/cm^2 (100-250 kg/cm^2). The emulsion formed was then dried in a spray-drier, wherein the warm air has a temperature of 200°C. The outcoming oil-powder mixture has a temperature of 70°C, which temperature was lowered to 20°C by passing a

Example 4 GLA granulate

Components

Borage oil-powder mixture (50% oil)	350 mg
Dextrose (EMDEX^{R})	250 mg
Hydroxy propyl starch	100 mg

The components were mixed to a granulate in the same way as described in Example 3.

Example 5 GLA-Vitamin B6 granulate

Components

Borage oil-powder mixture (50% oil)	350 mg
Dextrose (EMDEX^{R})	250 mg
Hydroxy propyl starch	100 mg
Pyridoxine chloride	20 mg

The components were mixed to a granulate in the same way as described in Example 3.

Example 6 EPA/DHA granulate

Components

Cod liver oil-powder mixture (50 % oil)	350 mg
Dextrose (EMDEX^{R})	250 mg
Methyl cellulose	15 mg

The components were mixed to a granulate in the same way as described in Example 3.

The granulate obtained in Example 3 was mixed with the other components and formed to tablets in the same way as described in Example 8.

Example 10 GLA-vitamin B6 tablet

Composition	Tablet content
GLA granulate	700 mg
Pyridoxine chloride	20 mg
Cellulose Avicel^{R}	100 mg
Fructose	40 mg
Citric acid	12 mg
Arom. lemon	28 mg
Average weight	900 mg

The granulate obtained in Example 4 was mixed with the other components and formed to tablets in the same way as described in Example 8.

Granulate containing GLA and tablets containing GLA can be prepared from black currant oil, evening primrose oil, wheat germ oil or biosynthesis optionally with additives in the same way as described in Examples 3-5 and 7-10.

Granulate and tablets containing EPA/DHA can be prepared from marine oils optionally with additives in the same way as described in Examples 6-10.

e) driven the dried granulate, optionally together with additives to desired size.

3. Granulate according to claims 1 or 2 wherein the oil-powder mixture containing 40 to 75 % (w/w) oil.

4. Granulate according to any of claims 1-3 wherein the oil-powder mixture containing 50 % (w/w) oil.

5. Granulate according to any of claims 1-4. wherein the oil is borage oil, cod liver oil or shark liver oil.

6. Granulate according to any of claims 1-5 wherein the water-soluble carrier is soybean protein.

7. Granulate according to any of claims 1 or 2 wherein the filler is a sugar or a modified sugar e.g. dextrose.

8. Granulate according to any of claims 1 or 2 wherein the binder is a polysaccharide or modified polysaccharide e.g. methyl cellulose, hydroxy propyl starch.

9. Granulate comprising an oil-powder mixture containing 50 % (w/w) borage oil and soybean protein in combination with dextrose and methyl cellulose or hydroxy propyl starch.

10. Granulate according to any of claims 1-9 containing an additive such as vitamins, minerals, antibiotics, hormones, cortisones, pollen products and ginseng products.

11. A method for manufacturing

(i) a granulate comprising an oil-powder mixture containing 2-75 % (w/w) vegetable oil and/or marine oil, wherein the essential fatty acids are selected from gamma-linolenic acid (GLA), eicosapentaenoic acid (EPA) and/or docosahexanenoic acid (DHA), and/or other marine oils and a water-soluble carrier, in combination with

19. Tablet according to claim 16 wherein the additive is lecithin and pollen products.

20. Use of a tablet according to any of claims 14-19 as a pharmaceutical product or as a dietary supplement product.

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

V. [X] OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE [1]

This international search report has not been established in respect of certain claims under Article 17(2) (a) for the following reasons:

1. [X] Claim numbers 20*) because they relate to subject matter not required to be searched by this Authority, namely:

Methods for treatment of the human or animal body by therapy [PCT Rule 39 (iv)]

*) (to the extent that terapeutical treatment is concerned)

2. [ ] Claim numbers....., because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claim numbers....., because they are dependent claims and are not drafted in accordance with the second and third sentences of PCT Rule 6.4(a).

VI. [ ] OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING [2]

This International Searching Authority found multiple inventions in this international application as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.
2. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:
3. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:
4. [ ] As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

Remark on Protest

- [ ] The additional search fees were accompanied by applicant's protest.
- [ ] No protest accompanied the payment of additional search fees.

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

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(54) Title: COMPOSITION FOR REDUCING PLASMA TRIGLYCERIDES, PLATELET AGGREGATION, AND OXIDATIVE CAPACITY

(57) Abstract: A composition comprising at least one unsaturated fatty acid, such as an omega-3 fatty acid; pantethine; and an antioxidant selected from the group consisting of Vitamin C, Vitamin E, tocotrienol, at least one carotenoid, at least one flavenoid, coenzyme Q10, and grape seed extract. Such active ingredients may be encapsulated in an encapsulating medium to form microparticles, which may be suspended in an aqueous solution. Such a composition reduces plasma triglyceride levels, platelet hyperaggregation, endothelium dysfunction, and tissue oxidative capacity, and thus reduces the risk of cardiovascular disease.

58, pgs. 163-169 (1999)). Within the myriad of identified biochemical events and factors contributing to cardiovascular disease, there are included hypertriglyceridemia, oxidized low-density lipoprotein (LDL), and platelet aggregation. It has been demonstrated in a variety of studies that hypertriglyceridemia (elevated plasma levels of triglycerides) is a risk factor for cardiovascular disease, particularly coronary artery disease. (Hokanson, et al., J. Cardiovasc. Risk, Vol. 3, pgs. 213-219 (1996); Stampfer, et al., JAMA, Vol. 11, pgs. 882-888 (1996); Patsch, et al., Arterioscler. Thromb., Vol. 12, pgs. 1336-1345 (1992)). In intervention studies wherein hypertriglyceridemia is reduced by the administration of pharmaceutical agents, the risk of cardiovascular disease also is reduced. (Ericsson, et al., Am. J. Cardiol., Vol. 80, pgs. 1125-1129 (1997); Ericsson, et al., Lancet, Vol. 347, pgs. 849-853 (1996); Rubins, et al., N. Engl. J. Med., Vol. 341, pgs. 410-418 (1999)). Plasma triglycerides contained within circulating very low density lipoprotein (VLDL) and low density lipoprotein (LDL) molecules potentiate cardiovascular disease by a variety of proposed mechanisms. (Reaven, et al., Circulation, Vol. 93, pgs. 1780-1783 (1996)).

Also, in addition to the increased amounts of triglycerides within plasma VLDL and LDL, the oxidation of plasma lipoproteins, particularly VLDL and LDL, renders these endogenous molecules more atherogenic. (Griffin, 1999; Holvoet, et al., Atherosclerosis, Vol. 137, Supp. S33-8 (1998); Holvoet, et al., FASEB J., Vol. 8, pgs. 1279-1284 (1994)). Therefore, reducing plasma triglyceride levels as well as the extent of oxidized plasma lipoprotein would be of therapeutic value in protecting the cardiovascular system from atherosclerotic

Omega-3 fatty acids, at doses from about 1 to 6g per day, reduce triglycerides, and in particular, reduce the amount of triglycerides within circulating VLDL and LDL. (Agren, et al., Eur. J. Clin. Nutr., Vol. 50, pgs. 765-771 (1996); Sirtori, et al., Atherosclerosis, Vol. 137, pgs. 419-427 (1998).) At low doses, i.e., 1 to 2 grams per day, omega-3 fatty acids provide beneficial effects to the immune system. (Tashiro, et al., Nutrition, Vol. 41, pgs. 551-553 (1998)). Thus, although the scope of the present invention is not to be limited to any theoretical reasoning, Applicant, in order to provide the beneficial effects of omega-3 fatty acids to the immune function, and to maintain an equivalent potency of an anti-hypertriglyceridemic effect, has provided a composition which combines at least one omega-3 fatty acid at a low but effective anti-hypertriglyceridemic dosage with another anti-hypertriglyceridemic agent having an independent mechanism of action.

Pantethine is another antihypertriglyceridemic drug. (Bertolini, et al., Int. J. Clin. Pharmacol. Ther. Toxicol., Vol. 24, pgs. 630-637 (1986); Arsenio, et al., Clin. Ther., Vol. 8, pgs. 537-545 (1986)) with a mechanism of action distinct from that of omega-3 fatty acids, and may be combined with omega-3 fatty acids to maintain an effective anti-hypertriglyceridemic response. Also, pantethine possesses anti-oxidant activity, and has been shown to reduce oxidation of lipoprotein lipids (Bon, et al., Atherosclerosis, Vol. 57, pgs. 99-106 (1985)).

Although Applicant does not intend to be limited to any theoretical reasoning, omega-3 fatty acids are lipids which may be oxidized into an inactive molecule, the combination of omega-3 fatty acids with pantethine may reduce the oxidation, and thus inactivation, of omega-3

preferred embodiment, the carotenoid is lycopene. Lycopene is a natural carotenoid derived from the tomato.

In another embodiment, the at least one antioxidant is Vitamin E, including α- and- γ- tocopherols. Vitamin E, like the carotenoids, inhibits oxidation reactions of LDL which form conjugated dienes and thiobarbituric acid reactive substances.

In another embodiment, the at least one antioxidant is tocotrienol.

In another embodiment, the at least one antioxidant is at least one flavenoid. Flavenoids inhibit oxidation reactions of LDL which form lipid peroxides. Preferably, the at least one flavenoid is selected from the group consisting of catechins, pycnogenol, theaflavins, and combinations thereof. More preferably, the at least one flavenoid is pycnogenol. Pycnogenol is derived from the bark of conifers, such as pine bark, and in particular, the bark of the maritime pine. Pycnogenol is described further in U.S. Patent No. 5,719,178, issued to Paull, et al.

In another embodiment, the at least one antioxidant is Vitamin C. Vitamin C, like the flavenoids, also inhibits oxidation reactions of LDL which form lipid peroxides. Vitamin C also prevents oxidation of carotenoids and Vitamin E if such substances are included along with Vitamin C in the composition.

In another embodiment, the at least one antioxidant is coenzyme Q10.

In another embodiment, the at least one antioxidant is grape seed extract.

Although the scope of the present invention is not intended to be limited to any theoretical reasoning, it is believed by Applicant that the combination of (i) at least one unsaturated fatty acid, such as at least one

particles of each of the at least one of the pantethine and the at least one antioxidant.

In another alternative, the encapsulating medium may encapsulate one or more of the components of the composition, individually or collectively, but does not encapsulate all of the components of the composition.

Materials from which the encapsulating medium may be formed include, but are not limited to, ethyl cellulose, hydroxypropylmethyl cellulose, hydroxypropyl cellulose, methyl cellulose, polyvinyl alcohol, polyvinyl acetate butyrate, styrene acrylate copolymers, acrylic acid ester copolymers, and gelatin polymers. Preferably, the encapsulating medium is formed from ethyl cellulose.

The at least one unsaturated fatty acid, and at least one of the pantethine and the at least one antioxidant may be encapsulated with the encapsulating medium into particles by any of a variety of processes known to those skilled in the art. Examples of such processes are described in Lieberman, Pharmaceutical Dosage Forms: Tablets, Vol. 1, Second Edition, pgs. 372-376 (1989); Jayne, Microencapsulation, Processes and Applications, pgs. 103-113 (1973-1974); U.S. Patent No. 3,300,332, issued to Gorham, et al., and U.S. Patent No. 5,393,533, issued to Versic.

In one embodiment, the at least one unsaturated fatty acid and at least one of the pantethine and at least one antioxidant are encapsulated into particles having a size of from about 10 microns to about 1,000 microns, preferably from about 10 microns to about 100 microns.

In a more preferred embodiment the composition, in addition to the microparticles herein above described, further comprises a liquid carrier. Most preferably, the liquid carrier includes water. Suitable liquid carriers

1,000 mg per drink volume, preferably from about 400 mg to about 900 mg per drink volume.

When Vitamin E is included as an antioxidant in the composition, the Vitamin E may be present in an amount of from about 200 International Units (IU) to about 1,000 IU per drink volume, preferably from about 400 IU to about 800 IU per drink volume.

When lycopene is included as an antioxidant in the composition, the lycopene may be present in an amount of from about 40 mg to about 90 mg per drink volume, preferably from about 55 mg to about 80 mg per drink volume.

When pycnogenol is included as an antioxidant in the composition, the pycnogenol may be present in an amount of from about 50 mg to about 500 mg per drink volume, preferably from about 100 mg to about 300 mg per drink volume.

The invention now will be described with respect to the following examples; however, the scope of the present invention is not intended to be limited thereby.

Example 1

A formulation was prepared by adding the following ingredients to a fruit drink (guava juice: water, guava puree, fruit juice concentrate containing 22% fruit juice).

1. Approximately 5 grams microencapsulated fish oil concentrate (with lemon flavor) containing approximately 350 mg of eicosapectaenoic acid and docosahexaenoic acid.

2. Approximately 1.5 grams of microencapsulated 50% pantethine powder.

3. Approximately 400 I.U. of powdered vitamin E.

consumed about 3 grams per day. After 19 days of treatment, mice were sacrificed at 4-6 hours after light onset on the 20th day of the study. Serum was collected for the analyses of serum triglyceride and total cholesterol levels.

The mean serum levels +/- S.E.M. of triglyceride and cholesterol for the three groups were as follows.

SERUM PARAMETER	CONTROL GROUP (ob/ob)	TEST GROUP (ob/ob)	LEAN GROUP (+/?)
Triglyceride	232+/- 30 mg/dl	68 +/- 6 mg/dl*	40 +/- 2 mg/dl
Cholesterol	83 +/- 6 mg/dl	54 +/- 5 mg/dl*	65 +/- 2 mg/dl

An asterisk denotes a significant change from the control group ($P<0.05$).

The addition of a formulation in accordance with the present invention to the diet of hyperlipidemic mice reduced the serum triglyceride level by 70% and the serum total cholesterol level by 34% to levels observed in normal lean mice.

The disclosure of all patents and publications, including published patent applications, are herein incorporated by reference to the same extent as if patent and publication specifically and individually were incorporated by reference.

It is to be understood, however, that the scope of the present invention is not to be limited to the specific embodiments described above. The invention may be practiced other than as particularly described and still be within the scope of the accompanying claims.

8. The composition of Claim 1 wherein said at least one antioxidant is a carotenoid.

9. The composition of Claim 8 wherein said carotenoid is lycopene.

10. The composition of Claim 1 wherein said at least one antioxidant is a flavenoid.

11. The composition of Claim 10 wherein said flavenoid is selected from the group consisting of pycnogenol, catechins, theaflavins, and combinations thereof.

12. The composition of Claim 11 wherein said flavenoid is pycnogenol.

13. The composition of Claim 1 wherein said at least one antioxidant is coenzyme Q10.

14. The composition of Claim 1 wherein said at least one antioxidant is grape seed extract.

15. The composition of Claim 1, and further comprising:

(d) an encapsulating medium enclosing said at least one unsaturated fatty acid, and at least one of said pantethine and said at least one antioxidant.

16. The composition of Claim 15 wherein said encapsulating medium is formed from a material selected from the group consisting of ethyl cellulose, hydroxypropylmethyl cellulose, hydroxypropyl cellulose, methyl cellulose, polyvinyl alcohol, polyvinyl acetate butyrate, styrene acrylate copolymers, acrylic acid ester copolymers, and gelatin polymers.

INTERNATIONAL SEARCH REPORT

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A. CLASSIFICATION OF SUBJECT MATTER
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U.S. : 424/439

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	Database MEDLINE on ACS.No. 86117408, SPITTLE, C.R. "Atherosclerosis and vitamin C". Lancet. December 1971, Vol. 2 (7737) pages 1280-1281. See abstract.	1-20, particularly 1, 5
Y	Databast CAPLUS on ACS. No.1999:374534, LOWE et al. "Carotenoid composition and antioxidant potential in subfractions of human low-density lipoprotein". Ann. Clin. Biochem. 1999, Vol. 36, No. 3, pages 323-332, See abstract.	1-20, particularly 1, 8
Y	WO 96/19217 A1 (HENKEL CORPORATION) 27 June 1996, See abstract.	1-20, particularly 1, 9
Y	Database CAPLUS on ACS. No. 1999:681203, SINGH et al. "Coenzyme Q10 and its role in heart disease". J. Clin. Biochem. Nutr. 1999, Vol. 26 No. 2, pages 109-118. See abstract.	1-20, particularly 1, 13
Y	Database PROMT on ACS. No. 1998:294983, "Anonymous". "Switch OTC drugs in Japan: H2 blockers dominate new ingredient approvals (part II)". Comline Biotechnology and Medical. 12 June 1998. pages N/A . See abstract.	1-20, particularly 1
Y	Database CAPLUS on ACS. No. 96192251, RONG et al. "Pycnogenol protects vascular endothelial cells from t-butyl hydroperoxide induced oxidant injury". Biotechnology Therapeutics. 1994-1995 Vol. 5 No.3-4 pages 117-126. See abstract.	1-20, particularly 1,10-12

☒ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

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(54) Title: ALERTNESS BAR

(57) Abstract: A nutritional composition for enhancing alertness comprising: carbohydrate including galactose, fat, protein, caffeine, and optional further ingredients, wherein the ratio of carbohydrate to protein is in the range of 2:1 to 4:1 by weight, and wherein the fat includes an effective quantity of phospholipids selected from: phosphatidyl choline and phosphatidyl serine and mixtures thereof.

lead to situations in which use of effective substances is sub-optimal because cell and neuronal function has been reduced, either by centrally mediated potentials or reduced metabolic maintenance.

Exercise places considerable demands on the use of fuels to provide energy for working muscle and other tissues, and building blocks to maintain cellular function in all tissues to support normal body function. These fuels and building blocks can be sourced from both endogenous and exogenous substrates primarily in the form of glycogen in liver and muscle, glucose, fatty acids and amino acids in plasma, lipids in adipose tissue and muscle, and proteins. Tissues are unable to function without at least one source of fuel and are only able to function maximally when more than one source is available. Even then there are restrictions on both intensity and endurance of what are normal activities because each fuel source is only of finite size. It is not surprising that the status of the human body changes between meals and in periods when reserves become depleted. It is at such a time that attention declines and the state of alertness is reduced. Alertness may decline, particularly during repetitive activities, and can be severely restricted if either or both of the exogenous fuel supplies to provide substrates or endogenous reserves previously built up during recovery are inadequate. The provision of specific nutrients is beneficial because these substrates add to those used from the body's endogenous sources. The provision of selected nutrients during such times can improve alertness. This is related both to the repletion of body reserves and the maintenance of healthy tissue. Limitations in the prior art restrict the design of the most efficacious formulations for these situations because antagonisms between nutrients and new synergies were not known. This invention addresses and seeks to overcome these limitations.

According to the present invention a nutritional composition for enhancing alertness comprises carbohydrate including galactose, fat, protein, caffeine and optional further ingredients;

wherein the ratio of carbohydrate to protein is in the range of 2:1 to 4:1;

and wherein the fat includes an effective quantity of phospholipid selected from phosphatidyl choline, phosphatidyl serine and mixtures thereof.

use at least 50% of phosphatidyl serine and phosphatidyl choline sourced from bovine and/or soy phospholipids. Use of soy products allows production of a vegetarian product.

The fat component, preferably includes about 5 to 10% mono-unsaturated fatty acids (MUFA) and about 10 to 15% poly-unsaturated fatty acids (PUFA).

The use of ingredients to supply beneficial proportions of omega-6 and omega-3 fatty acids is preferred. Fish oils, vegetable oils or a mixture of these may be used. Vegetable oils (wheat germ, flaxseed, safflower, soybean, cotton seed, sesame and sunflower) are good sources of linoleic acid (omega-6). Vegetable oils (flaxseed, soybean, walnut and wheat germ) are good sources of alpha linolenic acid (omega-3). Fish oils are also rich sources of these essential fatty acids. A combination of flaxseed oil (high in PUFA and linolenic acid) and wheat germ oil (high in PUFA, linoleic acid and vitamin E) is made with evening primrose oil (high in gamma linolenic acid) and starflower oil (borage oil, high in gamma linolenic acid). This may be used as a vegetarian alternative to use of fish oil (such as cod liver oil). The ideal ratio of omega-6 to omega-3 content may be 4-10:1. Thus within products of this invention in which the ratio of MUFA to PUFA may be between 1:3 to 1:1, that part that is PUFA may contain a ratio between 4-10:1 of omega-6 to omega-3 fatty acids from any or a combination of all the sources described.

The composition may be formulated as a chewable bar, biscuit, cookie or cake. Sugar confectionery, gum or other tablet or cereal composition may also be provided. Liquid drinks or powder or granular blends for rehydration into drinks may also be employed.

Percentages and other proportions used in the specification are by dry weight unless indicated otherwise. Percentages and proportions may be selected from ranges given to total 100%.

Macronutrients referred to below are carbohydrates, fat and protein, that is excluding minerals, stabilisers, fibre, caffeine and other ingredients.

use compositions of exogenous ingredients that provide one or more:

1) permit sustained and effective sources of fuels and building blocks for tissue maintenance, especially those tissues associated with alertness;
2) permit the most effective presentation of fuels to the body tissues;
3) effect maintenance or enhancement of alertness acutely following digestion and assimilation;
4) facilitate the maximum alertness potential during normal lifestyle; and
5) provide a synergy exclusive to the use of these ingredients.

The carbohydrate:protein ratio should be within the range 2:1 to 4:1 by energy or mass. This is 48 to 57.6% carbohydrate, 24 to 14.4% protein, 28% fat on an energy basis (ie by proportion of the total macronutrient energy available). Since fat has approximately twice the calorific value of carbohydrate or protein, this would equate to 56.9 to 68.2% carbohydrate 28.4 to 17.1% protein, 14.7% fat on a mass basis of macronutrients (ie by dry weight of macronutrients but not by weight of bar containing variable amount of moisture). However the ratio of carbohydrate to protein was 3:1 with variation of fat from 15% to 45% on an energy basis or 7.3% to 26.7% on a mass basis.

The carbohydrate:protein ratio in the prefered embodiment is 3:1 on an energy basis or by weight. Preferably this is 54% carbohydrate, 18% protein, 28% fat on an energy basis (ie by proportion of the total macronutrient energy available). Since fat has approximately twice the calorific value of carbohydrate or protein, this would equate preferably to 64% carbohydrate, 21.3% protein, 14.7% fat on a mass basis of macronutrients (ie by dry weight of macronutrients but not by weight of bar containing variable amount of moisture).

The specific carbohydrates include all those above (both as pure saccharides or wholesome organic nutrients) to yield or produce by digestion or otherwise monosaccharides to include galactose, glucose and fructose. The ratio of content (mono, di, oligo, poly and complex saccharides of each type, % by weight of carbohydrate content) may be 14% to 59% by weight galactose yielding, 71% to 29% by weight glucose yielding, 15% to 12% fructose yielding (to achieve 100% by weight of carbohydrate content). The

rice protein. Part of the protein content may be added as a hydrolysate e.g. wheat protein hydrolysate.

Flavour as necessary e.g. lemon, lime, blackcurrant, orange, citrus, cranberry, chocolate. The mixture is formulated such that these constituents give bars that range from chewy to dry according to taste. Water content may be adjusted accordingly. For example, a water content may range from 2 to 40%, preferably 10 to 30%, more preferably 15 to 20%. Suggested size and mass for energy bars could range from 50g to 150g. A typical bar may be 100g of mixed ingredients.

The invention is further described by means of example but not in any limitative sense.

The following table lists ingredients of preferred products in accordance with this invention.

Ingredient	Weight/%								
	A	B	C	D	E	F	General Range Lower limit-Upper limit	Prefered range	Model Bar
from flaxseed, sunflower, fish and olive or other vegetable or animal oils. (supply of omega 3/6 fatty acids).									
Conjugated Linoleic Acid (CLA)	-	-	-	-	1	1	0.5-2	1-1.5	1
Fibre (Sol.&Insol) e.g. oat bran Part of the fibre content may be in the form of pectin.	5	5	5	5	5	5	2-10	5-8	6.7
Vitamins A vitamin mix may be used to supply the complete range of vitamins.	10-100% RDA	10-100% RDA	10-100% RDA	10-100% RDA	10-100% RDA	10-100% RDA	10-100%RDA	40-60% RDA	50% RDA
Protein (50% of which is whey and casein of variable proportion, casseinates may be used in part). The proportion of protein to carbohydrate (total as above, is 1:3 by energy. 50% of protein may be from natural products such as nuts, seeds and flour (e.g. soy flour), also from soy or rice protein. Part of the protein content may be added as a hydrolysate e.g. wheat protein hydrolysate.	17.5	17.5	17.5	17.5	17.5	17.5	6-30	12-24	17.3
Flavours	1	1	1	1	1	1	1	1	1
Minerals To include Fe, Zn,Ca, and other essential minerals.	0-100% RDA	0-100% RDA	0-100% RDA	0-100% RDA	0-100% RDA	0-100% RDA	10-100%RDA	40-60% RDA	50% RDA
Stabilisers To include citrate, phosphate and other buffer systems.	2	2	2	2	2	2	2	2	2
Water	11	11	11	11	5	5	2-20	5-15	10
Phosphatidyl serine Part of the requirement may be in the form of egg or soy phospholipid	0.150	0.150	0.150	0.150	0.150	0.150	0.050-0.350	0.125-0.175	0.15
Phosphatidyl choline Part of the requirement may be in the form of egg or soy lecithin	0.125	0.125	0.125	0.125	0.125	0.125	0.050-0.250	0.100-0.175	0.125
Vitamin E	200 1U	200 IU	200 1U	200 IU	200 1U	200 IU	50-400 IU	150-250 IU	200 IU
Vitamin C	0.125	0.125	0.125	0.125	0.125	0.125	0.050-	0.100-	0.150

CLAIMS

1. A nutritional composition for enhancing alertness comprising:
carbohydrate including galactose,
fat,
protein,
caffeine,
and optional further ingredients,
wherein the ratio of carbohydrate to protein is in the range of 2:1 to 4:1 by weight,
and wherein the fat includes an effective quantity of phospholipids selected from: phosphatidyl choline and phosphatidyl serine and mixtures thereof.

2. A composition as claimed in claim 1 wherein the ratio is in the range 0.5:1 to 3.5:1.

3. A composition as claimed in claim 2 wherein the ratio is in the range 2.7:1 to 3.2:1.

4. A composition as claimed in claim 3 wherein the ratio is 3:1.

5. A composition as claimed in any preceding claim wherein the carbohydrate is selected from: galactose, fructose, sucrose, moltodextrin, refined and raw cane sugar, high fructose corn syrup, hydrolysed lactose, starches and complex polysaccharides and mixtures thereof.

6. A composition as claimed in claim 5 wherein at least 90% of the galactose content is as the monosaccharide.

7. A composition as claimed in any preceding claim wherein the caffeine is selected from caffeine, natural products containing caffeine and mixtures thereof.

8. A composition as claimed in any preceding claim wherein the amount of

19. A composition as claimed in any preceding claim wherein the protein includes glutamine dipeptide.

20. A composition as claimed in claim 19 wherein the amount of glutamine dipeptide is in the range of 5-15%.

21. A composition as claimed in any preceding claim including an antioxidant.

22. A composition as claimed in claim 21 wherein the antioxidant is selected from ascorbic acid, green tea extracts and mixtures thereof.

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
P,X	US 2002/150607 A1 (MANNING PAUL B ET AL) 17 October 2002 (2002-10-17) claims 1-3,5,15,16; example 3 page 9, column 1, paragraph 2 -column 2, paragraph 3	1-8,21, 22
A	WO 01 28360 A (MARATHADE LTD ;GALE RICHARD WILLIAM (GB); KING RODERICK FREDRICK G) 26 April 2001 (2001-04-26) claims 1,2; tables 1,2 page 1, paragraphs 1-4 page 2, paragraph 5 page 3, paragraphs 4,6	1-22
A	WO 99 65335 A (BELL STACEY J ;FORSE R ARMOUR (US); BETH ISRAEL HOSPITAL (US); BIS) 23 December 1999 (1999-12-23) claims 1,4,9,10,12,27 page 1, line 24 -page 2, line 4 page 4, line 1 -page 11, line 11 page 13, line 1 -page 14, line 29 page 15, line 16,30	1-22
A	WO 01 78522 A (PROCTER & GAMBLE) 25 October 2001 (2001-10-25) examples 21,22,26 page 18, line 30 -page 19, line 3 page 25, line 5-34	1-22

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(71) Applicant (*for AL, AM, AT, AZ, BA, BE, BF, BG, BJ, BR, BY, CF, CG, CH, CI, CM, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, FR, GA, GE, GN, GQ, GR, GW, HR, HU, ID, IS, IT, JP, KG, KP, KR, KZ, LR, LT, LU, LV, MA, MC, MD, MG, MK, ML, MR, MX, MZ, NA, NE, NI, NL, NO, PH, PL, PT, RO, RU, SE, SI, SK, SN, SY, TD, TG, TJ, TM, TN, TR, UA, UZ, VN, YU only*): **UNILEVER N.V.** [NL/NL]; Weena 455, NL-3013 AL Rotterdam (NL).

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: NUTRITION BAR

(57) Abstract: A nutrition bar comprising; 10 %wt or more of soy and/or rice protein, at least one transition metal or transition metal or transition metal compound, and 2 %wt or more of a humectant. The transition metal(s) or transition metalcompound(s) are in a substantially water insoluble form at 20 °C or the nutrition bar has an Aw of 0.45 or less and/or 1 %wt or more of the soy and/or rice protein is in the form of nuggets and the humectant is selected from polyols. The bars hase elevated levels of soy and/or rice protein, yet do not suffer unacceptable from a deterioration in taste or other organoleptic properties over time.

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and/or rice, often have undesirable (after)tastes or develop such undesirable tastes or aftertastes upon storage. In particular, with certain products comprising soy and/or rice proteins an off-flavour may develop upon storage. Also the appearance and/or texture of such foods may deteriorate over time.

EP-A-1,302,111 discloses dietary bar compositions comprising soy protein, and low levels of glycerol. Some of the examples of bar compositions further comprise sorbitol.

Joseph et al., US patent No 5,389,345 disclose an unbaked low calorie food bar comprising proteinaceous material which may be soy protein and a digestible carbohydrate which may be sorbitol or glycerin.

Gilles et al. US Patent No. 6,248,375 (Abbott Labs) discloses solid matrix materials designed for the person with diabetes. It includes a source of fructose in combination with at least one nonabsorbent carbohydrate. The two component carbohydrate system is said to blunt the postprandial carbohydrate response. One of the forms for administration mentioned is nutritional bars. Gilles et al. disclose in the examples nutritional bars comprising about 15 or 16 % by weight of soy protein, about 4.6% by weight of glycerin and a vitamin and mineral pre-mix comprising zinc, iron and copper. Choice dm® Bar is cited as a nutritional bar for people with diabetes and including 17.1% total calories as protein in the form of calcium caseinate, soy protein isolate, whey protein concentrate, toasted soybeans, soy nuggets (soy protein isolate, rice flour, malt, salt) and peanut butter. Gluc-O-Bar® is said to be a medical food designed for use in management of diabetes which includes up to 23% of total calories as protein in the form of soy protein

form of an energy bar. Soy protein mentioned as one of the possible proteins.

Kaufman WO 01/33976 (Children's Research Hospital) is directed to a method for treating a type 2 diabetic to decrease hypoglycemic episodes and/or diminish fluctuations in blood glucose outside of the normal range, which comprises administering to the subject in an effective appetite suppressing amount a food composition, which can be a bar, which includes a slowly absorbed complex carbohydrate such as uncooked cornstarch. Soy protein, whey protein and casein hydrolysate are mentioned as possible protein sources.

DeMichele et al. US Patent No. 6,444,700 (Abbott Labs) is directed to immunonutritional products said to be useful in reducing the immunological suppression said to result from stress. Solid nutritional compositions such as bars are mentioned. Soy proteins are mentioned as possible ingredients for the solid compositions.

Lanter et al. US Patent No. 5,683,739 is directed to extruded animal feed nuggets comprising between about 90 and 99 wt% of at least one protein containing ingredient and between 1 and 6 wt% added fat. The nugget is prepared by plasticizing a blend of at least one protein-containing ingredient, added fat, sulfur (if present), and water, extruding the plasticized blend to form an animal feed nugget, and drying the extruded nugget to a water content of less than about 12 wt%. Protein sources mentioned include oil seed meals such as soybean meal and cottonseed meal, and animal byproduct meals such as meat meal, poultry meal, blood meal, feather meal, and fish meal, plant byproduct meal such as wheat middlings, soybean hulls, and corn byproducts and microbial protein such as torula yeast and

The present invention is directed especially to a nutrition bar which incorporates elevated levels of soy and/or rice protein, at least one transition metal or transition metal compound, and about 2%wt or more of a humectant. In the nutrition bar the at least one transition metal or transition metal compound is in a substantially water insoluble form at 20^{o}C, or, the nutrition bar has an Aw of 0.45 or less, or, about 1%wt or more of the soy and/or rice protein in the bar is in the form of nuggets and the humectant is selected from the group consisting of polyols.

Thus according to a first aspect the present invention provides a nutritional bar comprising;

a) 10%wt or more of soy and/or rice protein, about 1%wt or more being in the form of nuggets,

b) at least one transition metal or transition metal compound, and

c) 2%wt or more of a humectant selected from the group consisting of polyols.

According to a second aspect the present invention provides a nutritional bar comprising;

a) 10%wt to 40%wt or more of soy and/or rice protein,

b) at least one transition metal or transition metal compound, and

c) 3 to 10%wt or more of glycerol humectant,

and wherein the nutrition bar has an Aw of 0.45 or less.

According to a third aspect the present invention provides a nutritional bar comprising;

a) 10%wt to 40%wt of soy and/or rice protein,

Except in the operating and comparative examples, or where otherwise explicitly indicated, all numbers in this description indicating amounts of material or conditions of reaction, physical properties of materials and/or use are to be understood as modified by the word "about." All amounts are by weight, based on the total weight of the relevant product, unless otherwise specified.

Unless stated otherwise or required by context, the terms "fat" and "oil" are used interchangeably herein.

Unless stated otherwise or required by context, the terms "nutritional bar(s)" and "nutrition bar(s)" are used interchangeably herein.

Unless stated otherwise, all percentages are by weight based on the total weight of the composition.

For a more complete explanation of the above and other features and advantages of the invention, reference should be made to the following description of the preferred embodiments. The preferred embodiments apply to all aspects of the invention and can be used as appropriate for each aspect.

Detailed Description of the Invention

Protein

The nutritional bars of the invention comprise about 10%wt or more in total of soy and/or rice protein based on the total weight of the composition. It is preferred that the nutritional bars comprise 12%wt to 40%wt, e.g. 12%wt to 35%wt of soy and/or

rice protein, more preferably 13%wt to 30%wt, most preferably 14%wt to 25%wt based on the total weight of the composition.

The soy protein may be present in any suitable form including as isolated soy protein, as soy protein concentrate or as soy protein hydrolysates. Sources of rice protein include rice flour and rice protein concentrate

Without wishing to be bound by theory, it is believed that soy and/or rice protein based nutritional bars may suffer from problems of off-flavour development etc because of the presence of free amino acid groups.

According to the first aspect of the invention, the nutritional bars comprise 1%wt or more soy and/or rice protein present in the composition, based on the total weight of the composition, in the form of nuggets (hereinafter protein nuggets). For the other aspects of the invention this is preferred. For all aspects of the invention it is especially preferred that the nutritional bars comprise 5%wt or more soy and/or rice protein in the form of nuggets, more preferably 10%wt or more. It is especially preferred that the nutritional bars comprise 5%wt to 25%wt soy and/or rice protein in the form of nuggets, especially 10%wt to 20%wt. It is preferred that 80%wt or more of the soy and/or rice protein in the bar is present in the form of nuggets, more preferably 90%wt or more, most preferably 95%wt or more, such as 100%wt.

The protein nuggets preferably comprise 50%wt to 100%wt of soy and/or rice protein, more preferably 55%wt to 100%wt, most preferably 60%wt to 95%wt, such as 75%wt to 95%wt based on the weight of the protein nuggets.

in the substantially water insoluble form by any suitable means. It is preferred that either a substantially water insoluble salt is used, or, that the metal or compound is substantially encapsulated in a suitable encapsulant is used to achieve the desired level of water insolubility.

It is advisable to ensure that the transition metal or transition metal compound is in a substantially water insoluble form at all processing temperatures to which the nutrition bar is subjected during its preparation and ideally also at $5^{o}C$ or more above the maximum temperature reached during preparation.

Any substantially water insoluble compound of a transition metal may be used according to the invention, especially substantially water insoluble inorganic compounds. Such compounds selected from oxides, carbonates and phosphates (including pyrophosphates) are preferred. If copper is used then copper carbonate is preferred. If iron is used then ferric pyrophosphate is preferred. If zinc is used then zinc oxide is preferred.

The nutrition bars of the invention, typically overall comprise up to 100%, typically up to 50%, such as 10 to 35% of the European 2003 RDA of the transition metal. The exact amount of the transition metal and/or transition metal compound will depend upon the type used. Typically the nutrition bars, per bar, will comprise one or more of up to 1 mg of manganese, up to 1.1 mg of copper, up to 9.5 mg of zinc and up to 16 mg of iron. More preferably the nutrition bars comprise one or more of up to 0.5 mg of manganese, up to 0.4 mg of copper, up to 3 mg of zinc and up to 5 mg of iron.

cereals such as soy, pea, maize and wheat and isolated soy proteins.

Carbohydrates which may be used as the entire encapsulant material, or as a part thereof, include mono or polysaccharides including, cellulose polymers and starches, (including hydrolysed and modified starches) and sugar alcohols. Suitable materials include gum arabic, carrageenan, agar agar, alginates, pectins and pectates.

Preferred encapsulants are carbohydrates such as alginates or pectins, especially including the sodium, potassium and calcium salts of alginates.

Mixtures of sodium caseinate and either gum arabic, carrageenan, agar agar, and gum arabic, are suitable. Similarly, beta-lactoglobulin and either gum arabic, carrageenan, agar agar, alginate or pectins, especially beta-lactoglobulin and gum arabic may be used.

It is preferred that the weight ratio of the transition metal and/or transition metal compound to the encapsulant is in the range of from 5:1 to 1:15, preferably 1:2 to 1:12, e.g. 1:5 to 1:10.

The transition metal or transition metal compound may be encapsulated by any suitable encapsulation technique as known in the art, such as coacervation or spraying on, and does not require further explanation here.

By the term "substantially water insoluble" is meant that the transition metal or transition metal compound does not substantially dissolve in water, in particular that it has a

invention, it is preferred that the nutrition bar has an Aw of 0.43 or less, most preferably of 0.40 or less. The determination of the Aw is within the normal skill of the skilled person and does not need to be described further here.

Fat/Carbohydrate

The source for any fat used in the nutrition bars, whether internal or external to the protein nugget, is preferably vegetable fat, such as for example, cocoa butter, illipe, shea, palm, palm kernal, sal, soybean, safflower, cottonseed, coconut, rapeseed, canola, corn and sunflower oils, or mixtures thereof. However, animal fats such as butter fat may also be used if consistent with the desired nutritional profile of the product. Preferably the amount of fat in either the protein nugget or the bar as a whole, is not more than 45 wt%, especially not more than 35 wt%, preferably from 0.5 to 20 wt%, still preferably from 1 to 15 wt%.

Carbohydrates can be used within the protein nuggets at levels of from 1%wt to about 35wt% of the protein nuggets. In addition to sweeteners mentioned below, examples of suitable carbohydrates include starches such as are contained in rice flour, flour, tapioca flour, tapioca starch, and whole wheat flour and mixtures thereof. Carbohydrates can be used outside the protein nuggets within the bar as well. Levels of carbohydrates in the bar as a whole will typically comprise from 5 wt% to 80 wt%, especially from 20% to 65 wt%, such as from 25% to 60 wt%.

Optional ingredients

If it is desired to include a bulking agent in the nutrition bars, within or external to the protein nuggets, a preferred bulking agent is inert polydextrose. Other conventional bulking

If desired, the protein nuggets and/or nutrition bar may include processing aids such as calcium chloride.

The nutritional bars may comprise one or more cholesterol lowering agents in conventional amounts. Any suitable, known, cholesterol lowering agent may be used, for example isoflavones, phytosterols, soy bean extracts, fish oil extracts, tea leaf extracts.

The food product may optionally comprise, in suitable amounts, one or more agents which may beneficially influence (post-prandial) energy metabolism and substrate utilisation, for example caffeine, flavonoids (including tea catechins, capsaicinoids and canitine).

The protein nuggets and/or nutrition bar may also include emulsifiers. Typical emulsifying agents may be phospholipids and proteins or esters of long chain fatty acids and a polyhydric alcohol. Lecithin is an example. Fatty acid esters of glycerol, polyglycerol esters of fatty acids, sorbitan esters of fatty acids and polyoxyethylene and polyoxypropylene esters of fatty acids may be used but organoleptic properties, or course, must be considered. Mono- and di-glycerides are preferred. If present in the nuggets, emulsifiers may be used in amounts of about 0.03% to 0.3%, preferably 0.05% to 0.1%. The same emulsifiers may also be present in the nutrition bar, again at levels overall of about 0.03% to 1%, preferably 0.05% to 0.7%. Emulsifiers may be used in combination, as appropriate.

Among fiber sources which may be included in the nutrition bars of the invention are fructose oligosaccharides such as inulin, soy fiber, fruit fibre e.g. apple, guar gum, gum arabic, gum

in sugar solids levels of up to 50 wt%, preferably from 5 to 18 wt%, especially from 10 to 17 wt% of the nutrition bar.

If it is desired to use artificial sweeteners, these may likewise be present in any protein nuggets or within the bar external to the nugget, provided that it does not interfere with processing. Any of the artificial sweeteners well known in the art may be used, such as aspartame, saccharine, Alitame® (obtainable from Pfizer), acesulfame K (obtainable from Hoechst), cyclamates, neotame, sucralose, mixtures thereof and the like. The sweeteners are used in varying amounts of about 0.005% to 1wt% on the bar, preferably 0.007% to 0.73% depending on the sweetener, for example. Aspartame may be used at a level of 0.05% to 0.15%, preferably at a level of 0.07% to 0.11%. Acesulfame K is preferred at a level of 0.09% to 0.15%.

Calcium is preferably present in the nutrition bars at from 10 to 30% USRDA, especially about 25% USRDA. The calcium source is preferably dicalcium phosphate. For example wt% levels of dicalcium phosphate may range from 0.5 to 1.5%. In a preferred embodiment, the product is fortified with one or more vitamins and/or minerals (in addition to those referred to above in the first to third aspects of the invention) and/or fiber sources, in addition to the calcium source. These may include any or all of the following:

Ascorbic acid (Vitamin C), Tocopheryl Acetate (Vitamin E), Biotin (Vitamin H), Vitamin A Palmitate, Niacinamide (Vitamin B3), Potassium Iodide, d-Calcium Pantothenate (Vitamin B5), Cyanocobalamin (Vitamin B12), Riboflavin (Vitamin B2), Thiamine Mononitrate (Vitamin B1), Molybdenum, Selenium, Calcium Carbonate, Calcium Lactate, Magnesium (e.g., as magnesium phosphate).

Manufacture of bars

The nutritional bars may be made by known methods provided that any protein nuggets are not exposed to temperatures which cause degradation of their ingredients, especially, the proteins or encapsulant if present.

Extruded nutritional bars may be made by cooking a syrup containing liquid (at ambient temperature) ingredients and then mixing with dry ingredients. The mixture is then extruded onto a conveyor belt and cut with a cutter. Any protein nuggets are included among the dry ingredients and should only be added to the syrup when the syrup is at a temperature below that at which any of the nugget components degrade. Supercritical fluid extrusion of the bar as a whole at reduced temperatures can also be considered. Syrup ingredients may include components such as corn syrup, glycerine, lecithin and soybean oil or other liquid oils. In addition to any protein nuggets, other dry components include grains, flours, maltodextrin and milk powders may be used.

Nutritional bars in the form of granola bars may be made by cooking the syrup, adding the dry ingredients, blending the syrup and dry ingredients in a blender, feeding the blended mix through rollers and cutting with a cutter.

The bars of the invention may be fully or partially coated, e.g. with milk chocolate or yogurt flavored coating. Suitable conventional coating methods may be used.

Typically, excluding moisture lost during processing, uncoated bars of the invention will be made from 30-70 wt% syrup, especially 35-65%, and 70-30 wt% dry ingredients, especially 65-35 wt%.

Example 1

Two Granola-style nutrition bars were made to the following compositions:

	A %wt	B %wt
Binder:		
Glucose syrup	8.903	11.861
Polydextrose syrup	9.90	10.0
Inulin syrup	4.6	4.6
Sugar	2.3	2.3
Pectose paste	5.0	5.0
Coconut oil	2.3	2.3
Lecithin	0.6	0.6
Glycerol	5.0	1.242
Invert syrup	4.9	4.9
Date paste	3.0	3.0
Corn oil	2.1	2.1
Flavourings	0.375	0.375
Colourings	0.144	0.144
Water loss	-3.20	-3.20
Dry material:		
Oatflakes	4.324	5.5
Coconut flakes, sweetened and shredded	2.2	2.2
Fruit fibre	4.15	4.15
Soy protein nuggets 1 *1	6.0	6.0
Soy protein nuggets 2 *2	23.5	23.1
Vitamin/mineral mix *3	3.904	3.904
Coating:		
Dairy coating	10.00	10.00
A_W	0.40 +/- 0.03	0.53 +/- 0.02
Bar weight	60.0 g	60.0 g

Bar B was prepared by the method for bar A except the first heating stage was to 225-230oF, 83 Brix, that invert syrup was added with the other binder ingredients and the date paste was added with the colourings and flavouring. The bar was cut into dimension of 11cm x 3.5cm x 1.9cm.

Results

The nutrition bars were stored under accelerated storage conditions at either 30oC or 36oC, or, normal storage at 20oC to assess them for off flavour development and a deterioration in the organoleptic properties. Bar A was stable after 4 months accelerated storage at 30oC which is the equivalent of more than 12 months storage at 20oC, showing no unacceptable off-flavour development and no unacceptable deterioration in other organoleptic properties. The bars were still chewy, moist and with a good taste after 12 months storage at 20oC. No unacceptable browning of the bar was observed. Bar B was stable for only 4 weeks at 36oC and 6 months at 20oC but thereafter quickly produced a nutty off-flavour and browning.

It should be understood of course that the specific forms of the invention herein illustrated and described are intended to be representative only, as certain changes may be made therein without departing from the clear teaching of the disclosure. Accordingly, reference should be made to the appended claims in determining the full scope.

8. A nutritional bar according to claim 7 wherein the triol comprises glycerol.

9. A nutritional bar according to any one of the preceding claims comprising 3%wt to 20%wt of the humectant.

10. A nutritional bar according to any one of the preceding claims wherein the humectant comprises 3%wt to 10%wt of glycerol.

11. A nutritional bar according to any one of the preceding claims wherein the at least one transition metal or transition metal compound is selected from the group consisting of chromium, manganese, iron, cobalt, nickel, copper, zinc, and their compounds and mixtures thereof.

12. A nutritional bar according to any one of the preceding claims wherein the at least one transition metal or transition metal compound is in a substantially water insoluble form at 20°C.

13. A nutritional bar according to claim 12 wherein the at least one transition metal or transition metal compound is substantially encapsulated in an encapsulation material.

14. A nutritional bar comprising;
    a) 10%wt to 40%wt of soy and/or rice protein,
    b) at least one transition metal or transition metal compound, and
    c) 3 to 10%wt or more of glycerol humectant,
    and wherein the nutrition bar has an Aw of 0.45 or less.

INTERNATIONAL SEARCH REPORT

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PCT/EP2004/006290

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A23L1/305 A23L1/304 A23L1/29 A23G3/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A23L A23G

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, FSTA, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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A	US 6 444 700 B1 (DEMICHELE STEPHEN J ET AL) 3 September 2002 (2002-09-03) cited in the application example 3	1-17
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A	US 5 418 010 A (JANDA JOSEPH ET AL) 23 May 1995 (1995-05-23) column 1, lines 19-27; claims 1-9	13,17

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

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"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
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